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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,831	03/26/2004	Thomas R. Kozel	031673-3000	7955

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,831	KOZEL ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 9-36* is/are pending in the application.

4a) Of the above claim(s) *1,10-14 and 23-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,15-22 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 9-36* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/05*.
4) ☐ Interview Summary (PTO-413), Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SDD

DETAILED ACTION

1. Applicants' Response to Restriction, received 15 August 2005, is acknowledged. Applicants elect, with traverse, Invention IV, claims 9, 15-20 and 22 drawn to immunoassays using antibody, classified in class 436, subclass 501. The traversal is on the grounds that the search and examination of the claims in groups I-V do not impose a serious burden upon the examiner. This is not found persuasive because the inventions are distinct for the reasons put forth in the original restriction requirement, have acquired a separate status in the art as shown by their different classification, and because while the searches may overlap, the searches are not coextensive, restriction for examination purposes as indicated is proper. The requirement is still deemed proper and is therefore made FINAL.

It is noted that claim 21 was inadvertently omitted from Invention IV and therefore will be included in the invention group.

Claim 9 has been amended. Claims 2-8 have been canceled. New claims 33-36 have been added. Claims 1 and 9-36 are pending. Claims 1, 10-14 and 23-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. Claims 9, 15-22 and 33-36 are under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is directed to an assay using an anti-PGA antibody comprising detecting the presence or absence of PGA in a sample wherein the anti-PGA is prepared by a specific mechanism. It is unclear how the anti-PGA antibody is prepared imparts any distinguishing characteristic over antibody raise against PGA by another method.

6. Claims 15-22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites "A method comprising detecting a level of soluble poly glutamic acid in a biological sample from a vertebrate." Because there is no recitation of the method except for the one step, it is unclear what is being claimed, i.e., is the claimed method merely the detection of a level of soluble polyglutamic acid in a biological sample from a vertebrate. Claims 16-22 depend from claim 15, but do not clarify the indefiniteness.

7. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is drawn to a method comprising detecting a level of soluble poly glutamic acid in a biological sample from a vertebrate, further comprising the detected level to "a reference level" of said soluble poly glutamic acid. It is unclear what are the metes and bounds of this

phrase. There is no reference, e.g., to a level in a control group, or the identity of the control group.

8. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, for lack of antecedent basis.

Claim 22 recites the limitation "method according to claim 19, wherein the reference level" in line 1. There is insufficient antecedent basis for this limitation in the claim because claim 19 nor 15 from which it depends recites a "reference level".

9. Claims 33-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of level of PGA in samples using anti-PGA, does not reasonably provide enablement for detection or staging of anthrax infection in light of applicants' comments, page 36, Example 7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a method for detecting or staging anthrax infection in a vertebrate of interest comprising contacting a biological saple prepared from said vertebrate with an anti-PGA antibody to detect a level of soluble PGA in said biological sample, wherein the level of soluble PGA in said biological sample is indicative of anthrax infection, or state thereof, in said vertebrate.

The specification teaches in Example 7, pages 36-37, that "PGA is produced by several *Bacillus* species that are likely to be encountered in the environment. Such exposure to either saprophytic *Bacillus* species or to *Bacillus anthracis* itself would lead to production of PGA antibodies. This is a common phenomenon in which exposure to naturally-occurring antigens leads to eventual production of high levels of antibodies to many capsular polysaccharides. The

results showed that normal adults produce anti-γdPGA IgG and IgM (Figure 10). The titers are normally distributed; some individuals have quite high levels of antibody." In addition, Schneerson et al (*PNAS*, 100(15):8945-8950 teach that "Other bacilli produce poly(γ-glutamic acid)(γPGA)" (page 8945, col 1, bottom).

The specification does not teach how to distinguish between levels of soluble PGA which are the result of "exposure to saprophytic *Bacillus* species" from exposure to *Bacillus anthracis*. Thus, the scope of the claims constitute merely an invitation to experiment without a reasonable expectation of success.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 9, 15, 16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Froman et al (*Journal of Reproduction and Fertility*, 88(2):405-410, 1990).

The claims are directed to an assay using an anti-PGA antibody (claim 9, 16, and 18) or any detection method (claim 15) comprising detecting the presence or absence of PGA in a sample.

Froman et al teach the claimed methods (Abstract; section **Materials and Methods**).

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

September 26, 2005